

REMARKS

I. Status of the Application

Claims 26 – 46 are pending in the Application. Claims 26, 45 and 46 have been amended to recite an implant support operatively connected within the reactor vessel. Support for this amendment is found, for example, at page 11, lines 1 – 3, which state, “[t]he implants like hip stems or acetabular cups and the like are hold [held] in place by special hooks fixed on the head-plate of the bioreactor.” The claim amendments are also supported by Fig. 1, which shows supports for implants operatively connected within the reactor vessel. Claims 47 – 49 have been added and support for the new claims may be found at least at page 11, lines 18 – 20.

Claims 26 – 28, 30 – 32, and 35 – 46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over US 6,087,003 (“Benoit”) in view of either US 3,606,860 (“Dunn”) or US 1,725,680 (“Zebulske”). Claims 33 – 34 stand rejected as being obvious over Benoit in view of US 4,166,536 (“Roberts”) and either Dunn or Zebulske. Claim 29 stands rejected as being obvious over Benoit in view of Roberts, US 5,055,272 (“Wheeler”), and either Dunn or Zebulske. Applicants respectfully traverse all rejections in view of the following remarks and the amendments presented herein.

II. Claims 26 – 28, 30 – 32, and 35 – 46 Are Not Obvious Over Benoit in View of Either Dunn or Zebulske

Claims 26 – 28, 30 – 32, and 35 – 46 stand rejected under § 103(a) as being unpatentable over Benoit in view of either Dunn or Zebulske. Applicants respectfully traverse this rejection. The Examiner asserts that Benoit teaches a coating apparatus having a reactor vessel R-2, heating element TC, stirrer, a plurality of inlets/outlets connected to the reactor and a controlled source of carbon dioxide operatively connected to an inlet. The Examiner admits that Benoit

fails to teach an implant support and end use of coating apparatus for coating an implant. The Examiner asserts that it would have been obvious to modify the Benoit apparatus by providing a support for the implant which is operatively connected to the vessel since it is conventional to operatively connect a support for an article being treated. The Examiner asserts that Dunn teaches a container and discharge piping that receives the coated material from the coating vessel, and therefore, cures the deficiency of Benoit. The Examiner also asserts that Zebulske teaches an inner support within the reactor, having an open inner container for the granular material within the reactor vessel to provide greater control for the coating process, and thus cures the defect in Benoit.

Applicants believe that the Examiner has failed to support a *prima facie* case of obviousness because no reference of record teaches or suggests all the limitations of Claim 26. Claim 26, as amended, describes a device for coating an implant comprising a vessel, a heating element, a support operatively connected within the reactor vessel, a stirrer, an inlet, an aperture, and a source of carbon dioxide. Benoit fails to teach or suggest a support operatively connected within a reactor. Applicants disclose on page 11, lines 1 – 3 in the Application, “[t]he implants like hip stems or acetabular cups and the like are hold [held] by special hooks fixed on the head-plate of the bioreactor.” The Examiner acknowledges on page 2 of the present Office Action that Benoit does not teach the implant support required by Claim 26. Neither Dunn nor Zebulske cure this defect of Benoit. Dunn fails to teach or suggest an implant support within the reactor vessel. The Examiner has admitted that Dunn teaches a support which is external to the reactor. Zebulske fails to teach or suggest an implant support within the reactor vessel. In contrast, the material being coated in Zebulske is flowing through the reactor and is in no way supported within the reactor (page 4, col. 1, lines 23 – 36). In contrast, Applicants’ implants are supported

by the implant support within the reactor vessel and are not flowing through the reactor vessel. Thus, the references relied upon to reject Claim 26 fail to teach or suggest all of its claim limitations.

agitation
Claims 27 and 28 are said to be obvious in light of Benoit in view of either Dunn or Zebulske. Claims 27 and 28 are nonobvious by virtue of their dependency, either directly or indirectly, from Claim 26 for the reasons presented above relating to Claim 26. Claim 28 is nonobvious for the additional reason that Claim 28 exemplifies unexpected results. Indeed, achieving successful results using a spinning speed of 100 RPM is a surprising unexpected result. When referring to coating solid particles, Benoit teaches at column 9, lines 60 – 65, “[a]gitation speeds can normally vary between 200 and 400 RPM.” Further, of the 25 examples presented by Benoit, the least amount of agitation is 210 RPM (see Example 20), which is more than twice the amount of agitation claimed in Claim 28. Thus, Benoit does not teach or suggest using agitation speeds less than 200 RPM and neither Dunn nor Zebulske cure this defect. Accordingly, there is no suggestion to use an agitation speed less than 200 RPM. Therefore, Applicants submit that Claim 28 is patentable for this additional reason.

Claims 30 and 31 stand rejected as being obvious over Benoit in view of either Dunn or Zebulske. The Examiner asserts that it would be obvious to use the solenoid or electro-valve described in Claim 31 in the apparatus of Benoit. Claims 30 and 31 are nonobvious by virtue of their dependency, either directly or indirectly, from Claim 26 for the reasons presented above relating to Claim 26. Applicants further believe that Claims 30 and 31 are nonobvious for the additional reason that there is no motivation to a person of ordinary skill to substitute a standard valve with a solenoid or electro-valve because there is no reason to believe from Benoit that a

standard valve is inadequate for this particular application. Thus, Applicants submit that Claims 30 and 31 are not obvious in this aspect as well.

Claims 35 and 36 stand rejected as being obvious over Benoit in view of either Dunn or Zebulske because Benoit teaches the use of a 1.5 L autoclave. Claims 35 and 36 are nonobvious by virtue of their direct dependency from Claim 26 for the reasons presented above relating to Claim 26. Further, there are no cited references of record, which suggest to a person of ordinary skill to modify Benoit to employ a reactor vessel having a capacity other than 1.5 L. Thus, Applicants deem this rejection to be overcome for this additional reason as well.

Claims 37 – 39 stand rejected as being obvious over Benoit in view of either Dunn or Zebulske. Claims 37 – 39 are nonobvious by virtue of their direct dependency from Claim 26 for the reasons presented above relating to Claim 26. Thus, Claims 37 and 39 are deemed nonobvious.

Thermo circulator
Claim 38 stands rejected as being obvious over the teaching of Benoit in view of either Dunn or Zebulske. Claim 38 is nonobvious by virtue of its direct dependency from Claim 26 for the reasons presented above relating to Claim 26. Applicants respectfully traverse this rejection for the additional reason that the cited reference merely describes a heat exchanger for heating; Benoit does not teach or suggest a thermo-circulator capable of heating and cooling as described by Applicants. See page 10, lines 35 – 36 of the application. As the Examiner has made no reference of record teaching or suggesting this claim limitation, Applicants deem this rejection overcome for this additional reason.

Claims 41 and 42 stand rejected as being obvious over Benoit in view of either Dunn or Zebulske. Claims 41 and 42 are nonobvious by virtue of their dependency, either directly or indirectly, from Claim 26 for the reasons presented above relating to Claim 26. Applicants

respectfully traverse this rejection for the additional reason that the Examiner is applying an improper “obvious to try” rationale. Benoit merely provides guidance as to there being an advantage of controlling temperature and pressure. The guidance of Benoit, however, stops there; it does not teach or suggest using automation. While it is arguably “obvious to try” to control temperature and pressure via an automated system, it is an improper basis for an obvious rejection. Thus, Applicants deem Claims 41 and 42 to be nonobvious for this additional reason.

Claims 43 and 44 stand rejected as being obvious over Benoit in view of either Dunn or Zebulske. Claims 43 and 44 are nonobvious by virtue of their dependency, either directly or indirectly, from Claim 26 for the reasons presented above relating to Claim 26. Applicants traverse this rejection for the additional reason that the Examiner is providing an improper obvious to try rationale. The Examiner states that it would have been obvious to provide a filter membrane cell and optimize the pore size of the membrane cell. Applicants believe, however, that the Examiner is utilizing an improper “obvious to try” rationale. Benoit provides no indication as to which parameters are critical and no direction as to which of many possible choices is likely to be successful. Benoit merely mentions at column 11, line 53 that the apparatus is equipped with a filtering device. Thus, for this reason and those discussed herein above, Applicants deem Claims 43 and 44 nonobvious.

Claim 32 stands rejected as being obvious over Benoit in view of either Dunn or Zebulske. Claim 32 is nonobvious by virtue of its direct dependency from Claim 26 for the reasons presented above relating to Claim 26. Applicants respectfully traverse this rejection for the additional reason that Benoit fails to teach or suggest equipping the apparatus with an electrode. Further, Benoit does not suggest that one would even be concerned with the pH within the reactor. Thus, because Benoit fails to teach or suggest all of its claim limitations and

neither Dunn nor Zebulske cure the deficiency in Benoit's teaching, Applicants deem Claim 32 nonobvious.

Claim 45 stands rejected as being obvious over Benoit in view of either Dunn or Zebulske. Applicants respectfully traverse this rejection. Applicants renew the above comments relating to Claim 26, 27, 30, 32 and 39. Benoit, therefore, does not teach or suggest all of the limitations of Claim 45 (e.g. an implant support or an aperture) and neither Dunn nor Zebulske remedy the deficiency, Applicants deem Claim 45 patentable.

Claim 46 stands rejected as being obvious over Benoit in view of either Dunn or Zebulske. Applicants respectfully traverse this rejection. The above comments relating to Claims 26, 41 and 45 apply here and are incorporated by reference. As Benoit does not teach or suggest all of the limitations of Claim 46 (e.g. an implant support or an aperture) and neither Dunn nor Zebulske remedy the deficiency, Applicants deem Claim 46 patentable.

III. Claims 33 – 34 Are Not Obvious Over Benoit in View of Roberts and Either Dunn or Zebulske

Claims 33 – 34 stand rejected as being obvious over Benoit in view of Roberts and either Dunn or Zebulske. The Examiner admits on page 5, paragraph 2 of the office action that Benoit fails to disclose the reactor vessel fashioned from stainless steel including a coating to avoid deposition or incrustation of carbonate and calcium phosphate. The Examiner, however, asserts that Roberts provides a lining of polytetrafluoroethylene on a metal reaction vessel that is conventionally a stainless steel material to provide greater corrosion resistance. The Examiner then asserts that it would have been obvious to provide the Benoit reaction vessel with a polytetrafluoroethylene lining taught by Roberts.

Applicants respectfully traverse this rejection.

Claims 33 – 34 are nonobvious by virtue of their direct dependency from Claim 26 for the reasons presented above relating to Claim 26. Namely, Benoit does not teach or suggest an implant support within the reactor vessel or an aperture. Neither Roberts nor Dunn, Zebulske, or any other reference of record cures this deficiency.

In addition, Applicants believe that the combination of Benoit and Roberts is improper because there is no motivation to combine these references. In fact, Roberts is concerned with protecting a metallic vessel from corrosive chemicals (i.e., chemicals that are highly acidic or basic). In contrast, Claims 33 and 34 are concerned with preventing deposits of carbonated calcium phosphate (a relatively innocuous compound). Therefore, the nature of the problem-to-be solved is not similar enough to motivate the combination of references. Further, neither reference suggests that a coating made of, for example polytetrafluoroethylene, would be suitable for preventing deposits of carbonated calcium phosphate on a surface. In addition, neither Dunn nor Zebulske cure the deficiencies of the combination of Benoit and Roberts for the reasons discussed above. Thus, Claims 33 and 34 are not obvious for the additional reason that the combination of references is improper.

IV. Claim 29 Is Not Obvious Over Benoit in View of Roberts and Wheeler and Either Dunn or Zebulske

Claim 29, which is dependent from Claim 26, stands rejected as being obvious over Benoit in view of Roberts and Wheeler and either Dunn or Zebulske. The Examiner admits at page 5, paragraph 3 of the Office Action that Benoit fails to teach a porous sparger. The Examiner asserts, however, that it would have been obvious to use any conventional means to introduce carbon dioxide into the Benoit reactor vessel by providing a porous sparger because it is conventional to introduce gaseous components into a reactor using a sparger to more

thoroughly disperse the gaseous component in a vessel. The Examiner also asserts that it would be obvious to use a sparger producing microbubbles by the porous sparger as taught by Wheeler for the obvious advantage of greater dispersal within the liquid.

Applicants respectfully traverse this rejection.

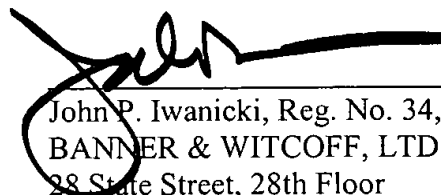
As discussed above, Claim 29 is nonobvious because Benoit fails to teach or suggest a porous sparger, an implant support within the reactor vessel, and an aperture. Roberts and Wheeler and either Dunn or Zebulske do not correct these deficiencies of Benoit by teaching an implant support within the reactor vessel or an aperture. Thus, the present rejection is deemed overcome because there are no references of record that teach or suggest all of the limitations of Claim 29.

V. Conclusion

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of all pending claims. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

Dated: July 22, 2003



John P. Iwanicki, Reg. No. 34,628
BANNER & WITCOFF, LTD.
28 State Street, 28th Floor
Boston, MA 02109
(617) 720-9600